DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

MN0028



January 5, 2001

**WARNING LETTER**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

**Refer to MIN 01 - 22**

Cheryl Hermann
Vice President, Clinical Systems
Allina Medical Group
8450 City Centre Drive
Woodbury, Minnesota 55125

Dear Ms. Hermann:

On December 13, 2000, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility, Allina Medical Clinic of Cottage Grove, at 8611 West Point Douglas Road, Cottage Grove, MN 55016 (FDA certificate #215020). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Repeat Level 2 and Level 2 findings were documented at your facility:

Repeat Level 2 Non-Compliance:

1. Two of six randomly selected mammography reports reviewed did not contain an approved assessment category.

Level 2 Non-Compliance:

2. The written procedure for handling mammography consumer complaints is incomplete in that it lacks all of the mandatory elements.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection. Item #1 was also cited during the 1999 inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

FDA acknowledges that Melody Walsh, R.T.(R)(M) from your site responded to the above non-compliances via a letter postmarked December 30, 2000. Because of the repeat nature of one of the non-compliances this letter is intended to alert senior management to the observed non-compliances. Note: As appropriate, your corrective actions regarding these issues should be directed towards all Allina sites, not just this single location. Due to the repeat nature of one of the non-compliances, a check-and-balance system should be developed to avoid a recurrence of this issue.

Please explain to this office in writing within 15 working days from the date you received this letter:

- each step your facility is taking to prevent the recurrence of similar violations;
- sample records that demonstrate proper records keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

James A. Rahto
Director
Minneapolis District

TWG/ccl

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